DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: MULTAQ
Patent Nos.: 5,223,510
7,323,493
Docket Nos.: FDA-2010-E-0040
FDA-2010-E-0039

OCT 26 2010

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,223,510 and 7,323,493, filed by Sanofi-Aventis, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for MULTAQ (dronedarone hydrochloride), the human drug product claimed by the patents.

The total length of the regulatory review period for MULTAQ (dronedarone hydrochloride) is 5,076 days. Of this time, 3,593 days occurred during the testing phase and 1,483 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 10, 1995.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 10, 1995.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: June 10, 2005.

   FDA has verified the applicant's claim that the first new drug application (NDA) for MULTAQ (NDA 21-913) was submitted on June 10, 2005.

3. The date the application was approved: July 1, 2009.

   FDA has verified the applicant's claim that NDA 22-425 for MULTAQ was approved on July 1, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: John D. Conway
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